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13. ABSTRACT *(Maximum 200 Words)*

The National Materials Advisory Board (NMAB) held the second BEMA Roundtable meeting on 04-05 December 2000, at the National Reseach Council (NRC), Washington DC. The invited speakers were Dr. David Feigal, Director for the Center for Devices and Radiological Health, US Food and Drug Administration; Prof Henry Piehler, Department of Materials Science and Engineering, Carnegie-Mellon University; Prof Henry Rack, Department of Ceramic and Materials Engineering, Clemson University; and Mark Heller, Senior Partner, Hale and Dorr LLP. The speakers addressed the topic biomaterials research innovation and risk. At this meeting, the membership decided to hold a major meeting focusing on "pathways to innovation". A smaller group was formed to work on the planning for this meeting.

NMAB held a third BEMA meeting on 10 June 2001 at NRC, Washington DC. The meeting goals were to present technical briefs on device innovation and science-based testing issues, present and discuss the current plan for the "pathways to innovation" meeting, and start the planning for a "science-based testing" meeting. The technical speakers were Gary Fischman, U Illinois Chicago; Tom Fogarty, Stanford; and Bill Regnault, FDA. A "science-based testing" planning group was created, analogous to the "pathways to innovation group", with a target of May-June 2002 to hold the meeting.

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Introduction

The Biomedical Engineering Materials and Applications (BEMA) Roundtable will provide a forum for identifying major opportunities for applying engineering principles to create and improve clinical performance of medically useful materials and devices, including implants, as well as for discussion of strategies for overcoming obstacles—technical, legal, or cultural—that impede transition of new materials and devices to clinical application.

Body

Roundtable Meetings

The National Materials Advisory Board (NMAB) held the second BEMA Roundtable meeting on December 4-5 2000, in Washington DC. The invited speakers were Dr. David Feigal, Director for the Center for Devices and Radiological Health, US Food and Drug Administration; Prof. Henry Piehler, Department of Materials Science and Engineering, Carnegie-Mellon University; Prof. Henry Rack, Department of Ceramic and Materials Engineering, Clemson University; and Mark Heller, Senior Partner, Hale and Dorr LLP. The speakers addressed the topic biomaterials research innovation and risk.

The membership decided to hold a major meeting focusing on "pathways to innovation". A smaller group was formed to work on the planning for this meeting. The planning group members are Sue Janicki, Dow; Ron Sahatjian, Boston Scientific; Paul Citron, Medtronic; Dianne Rekow, NJAIMS; Bill Regnault, FDA.

The NMAB held a third meeting on June 10 2001, in Washington DC. The meeting goals were to present technical briefs on device innovation and science-based testing issues, present and discuss the current plan for the "pathways to innovation" meeting, and start the planning for a "science-based testing" meeting. The technical speakers were Gary Fischman, U Illinois Chicago; Tom Fogarty, Stanford; and Bill Regnault, FDA. The BEMA members reviewed and discussed the planning for the October pathways to innovation meeting., including identification of potential invitees and speakers. A "science-based testing" planning group was also created, with a target of May-June 2002 to hold the meeting as a follow-on to the pathways to innovation meeting.

"Pathways to Innovation" Planning Group

The BEMA "pathways" planning group has met monthly via conference call, and has produced a draft agenda. The meeting will be held on 04-05 October 2001 in Washington DC. The keynote speaker will be the inventor of the stent, Julio Palmaz. The meeting will run for 1.5 days and consist of focused talks/discussion on barriers and pathways to innovation, and the effect of the Biomaterials Access Assurance Act on biomaterials availability. The meeting will also include breakout sessions for attendees to examine solutions to innovation barriers and materials access barriers from various viewpoints (e.g., regulatory, legal, commercial). The main speakers for the "pathways" meeting have been identified and have agreed to attend. The planning group's next set of action items include:

1) Develop a list of potential general attendees (attendee list partitioned by government, academia, and industry, with specific planning group members responsible for each organization)

2) Contact Advanced Tissue Sciences regarding their interest in a potential presentation on tissue engineering, and their philosophy for using new biomaterials

3) Produce a draft invitation letter to the large supplier attorneys (key point that the letter must address is the Freedom of Information Act and how it applies to this meeting).

The planning group has also considered the desired style/organization of the breakout sessions. The key questions are what should the session foci be (e.g., by government/industry/academia, or by raw materials supplier/device manufacturer/policy-legal) and how should we partition the attendees for the breakout sessions (e.g., their choice of which session to attend, assign sessions, identify key players to attend certain

sessions and let the other choose on their own). These questions will be answered more clearly as the meeting attendee list solidifies.

Key Research Accomplishments

- Two BEMA meetings held, covering topics on biomaterials research innovations and risk, device innovation, and science-based testing
- Formation of a "pathways to innovation" planning group
- Formation of a "science-based testing" planning group
- Draft agenda developed for the pathways meeting (see Appendix A)
- Main speakers for the pathways meeting identified and invited

Reportable Outcomes

- Presentations by
  - Dr. David Feigal, Director for the Center for Devices and Radiological Health, US Food and Drug Administration; and Mark Heller, Senior Partner, Hale and Dorr LLP, **Perspectives on Medical Devices**
  - Prof. Henry Piehler, Department of Materials Science and Engineering, Carnegie-Mellon University, **Biomedical Device Innovation and Risk**
  - Prof. Henry Rack, Department of Ceramic and Materials Engineering, Clemson University, **Advanced Biometallic Materials Innovation**
  - Gary Fischman, U Illinois Chicago, **Science-based Biomaterials Testing**
  - Tom Fogarty, Stanford, **The Influence of Materials Access and Materials Testing on Medical Device Innovation**
  - Bill Regnault, FDA, **Science-based Biomaterials Testing at FDA**

Conclusions

The BEMA Roundtable held two meetings in the past year, providing forums to discuss biomaterials innovation and risk, device innovation, and science-based biomaterials testing. The Roundtable formed a "pathways to innovation" planning group and a "science-based testing" planning group. Each group has been charged with organizing their respective meetings. The pathways to innovation meeting is scheduled for 04-05 October 2001, and the science-based testing meeting is targeted for May-June 2002. A draft agenda has been developed for the pathways meeting, and main speakers have been identified and invited.

THE NATIONAL ACADEMIES

Advisers to the Nation on Science, Engineering, and Medicine

National Academy of Sciences
National Academy of Engineering
Institute of Medicine
National Research Council

National Materials Advisory Board

APPENDIX A

Biomedical Engineering Materials and Applications Roundtable

National Research Council
Cecil and Ida Green Building, Room 130
2001 Wisconsin Ave NW
Washington DC 20418
October 4-5, 2001

AGENDA

Meeting Objectives

- Gauge the effects of biomaterials shortages and current status.
- Identify key barriers to biomaterials availability.
- Provide opportunities to explore with key stakeholders and decision makers future options in assuring biomaterials availability.

October 4, 2001

7:30 am	BREAKFAST	All
8:00	Welcome and call to order	Robert Nerem, Chair
8:15	Review of BEMA and goals of this meeting	Robert Nerem, Chair
8:30	FDA regulatory perspectives	David Feigal
9:15	Biomaterials Access Assurance Act: Legal perspective #1 (intent of the Act)	Ron Green
9:30	Biomaterials Access Assurance Act: Legal perspective #2 (actual effects of the Act, how is it working)	Supplier attorney(s)
10:00	Panel Discussion on Biomaterials Access Assurance Act	Ron Green, supplier attorneys
11:15	BREAK	
11:30	Morning review	Robert Nerem, Chair
Noon	LUNCH and LUNCHEON SPEAKER	
1:15 PM	Case study #1, industry-to-industry	Ron Sahatjian, Paul Citron
1:45	Discussion	All
2:00	Case study #2, academia-to-industry	Alan Goldstein
2:30	Discussion	All

3:00	Special presentation	Julio Palmaz
3:30	Discussion	All
4:00	BREAK	All
4:15	Begin breakout session organization	All
5:15	Day 1 review and discussion	Robert Nerem, Chair
5:30	**ADJOURN**	All
	Reception	All

October 5, 2001

7:30 am	BREAKFAST	All
8:00 am	Call to order and Day 1 review	Robert Nerem, Chair
8:15	Breakout sessions (need to determine the appropriate breakout groups: Academia/industry/gov't? Supplier/device manufacturer/legal-legislative?	All
10:15	BREAK	All
10:30	Summary of breakout session discussions	Robert Nerem, Chair
11:00	Open discussion	All
12:00 pm	LUNCH	All
1:00	**ADJOURN**	All